

US EPA ARCHIVE DOCUMENT



NAFTA Technical Working Group on Pesticides
Grupo de Trabajo Técnico del TLCAN sobre Plaguicidas
Groupe de travail technique de l'ALENA sur les pesticides

Global Harmonization of Microbial Pesticide Requirements: *OECD Data Evaluation Templates*

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Data Evaluation Templates – Purpose

- Evaluation templates are used to review the scientific studies that are submitted to support applications to register pest control products
 - Templates capture specific data components and record the reviewer's conclusions and rationales that are based on each data set
 - Executive summaries from templates are used to create an overall science monograph (i.e., review document) on which the regulatory decision is based

Data Evaluation Templates – Purpose

- PMRA encourages study directors to use the evaluation templates during the preparation of the studies and to create their study reports
 - The level of detail, however, should be the same as would normally be included in a study report
 - Their early use provides significant benefits to PMRA evaluators and industry and result in consistency of content and format and the facilitation of the evaluation process

Microbial Evaluation Templates – History

- Data evaluation templates for microbial pest control agents and products were developed because templates for chemical pesticides were deemed inadequate to cover pathogenicity and infectivity end-points
- PMRA initiated this template project in response to the completion of NAFTA-harmonized chemical pesticide evaluation templates
- Early drafts of microbial templates were modelled after chemical templates for health and environment test data
 - Health (toxicology) and environmental fate/effects templates followed different formats (distinct “look and feel”)

Microbial Evaluation Templates – History

- Microbial templates evolved as new test guidelines/protocols for microorganisms became available (e.g., Environment Canada EPS 1/RM/44, March 2004)
- Developed templates for waiver rationales, mainly for environmental toxicology and fate
 - Adapted from U.S. EPA guidance to registrants on building justifications for data waivers
- PMRA also developed templates for review of published literature (core papers and mini-literature reviews) as well as exposure templates (occupational/bystander and dietary assessments)

Microbial Evaluation Templates – History

- “Waiver Request”, “Published Study” and “Published Literature” headings were appended to each study template to eliminate the necessity of numerous templates for each guideline requirement

(For a waiver request, otherwise delete)

- I. **WAIVER RATIONALE:** *[Summarize the information and/or data presented by the author.]*

The waiver request is based on the following rationales:

A. Increased environmental exposure to *[name of active ingredient]*, due to use of the end-use product *[product name]*, will be minimal. *[Company may provide further elaboration: Give the natural habitat of the MPCA. Is it ubiquitous in nature (give geographical distribution); has the MPCA, and/or phylogenetically close species/strains, been isolated from soil/streams/ponds/lakes and a variety of plant surfaces including (name) crops/vegetables/fruits? Give the known natural concentration of the MPCA in CFU/(weight-volume-surface area) in these environmental niches.]*

Microbial Evaluation Templates

- Template header and signature lines were revised as per NAFTA templates for conventional chemical pesticides

New
Templates

Pelagic Aquatic Arthropods - <i>[species, "Waiver Request", "Review of Published Study" or "Review of Published Literature"]</i>			/ 1
Sub. No. / Company code TECHNICAL (Active code) and/or MPCA / Active Code			
Primary Reviewer:		_____	Date:
		<i>[Name or No., title, and affiliation]</i>	
Secondary Reviewer:		_____	Date:
		<i>[Name or No., title, and affiliation]</i>	
Approved by:		_____	Date:
		<i>[Name or No., title, and affiliation]</i>	

<u>REQUIREMENT:</u>	PMRA Data Code:	M9.5.2–Aquatic arthropods	
	U.S. EPA Requirement:	885.4240, 885.4280	
	OECD Data Code:	IIM 8.3, IIIM 10.2	
<u>TEST MATERIAL (PURITY):</u>	<i>[use name of material tested as referred to in the study and include its potency, lot no., biological activity or concentration per unit weight or volume] or [insert TGA and EP names if a waiver request is made]</i>		

Microbial Evaluation Templates

- Improved consistency between health and environment templates

Previous Health Template

I. MATERIALS AND METHODS		
A. MATERIALS:		
1. Test Material:	<i>[as named in study]</i>	
Description:	<i>[e.g. technical, nature, colour, stability]</i>	
Lot/Batch#:		
Purity:		
CAS#:		
Storage conditions:	<i>[Describe how the test sample was stored and comment on the stability of sample under these conditions.]</i>	
Microbiology:	<i>[Verification of concentration/homogeneity as necessary]</i>	
2. Sample Preparation: <i>[Describe all sample preparation procedures.]</i>		
3. Controls: <i>[if applicable] [List all controls (e.g. heat-killed) and, if applicable, describe how the samples were prepared.]</i>		
4. Test animals:		
Species:		
Strain:		
Age/weight at dosing:		
Source:		
Housing:		
Diet:	<i>(describe) ad libitum</i>	
Water:	<i>(describe) ad libitum</i>	
Environmental conditions:	Temperature:	°C
	Humidity:	%
	Air changes:	/hr
	Photoperiod:	hr dark/ hr light
Acclimation period:		

Previous Environment Template

I. MATERIALS AND METHODS	
<u>GUIDELINE FOLLOWED:</u>	<i>[Indicate which of the following guidelines were followed most closely in testing, and whether the guideline was developed for the toxicity testing of chemical agents or for the toxicity and infectivity/pathogenicity [or] toxicity testing of microbial agents. PMRA DIR 2001-02 Part 9.2¹ Environment Canada EPS 1/RM/44 Section 14.1¹ U.S. EPA 885.4050-Avian oral, Tier I¹ U.S. EPA 850.2100-Avian acute oral toxicity test² OECD Guideline 223 (Draft)²]</i>
<p>1. Guideline designed to test acute oral infectivity and pathogenicity of microbial agents.</p> <p>2. Guideline designed to test acute oral toxicity of chemical agents.</p>	
<u>COMPLIANCE:</u>	<i>[Specify the GLP standard used. Indicate if signed and dated GLP, Quality Assurance and Data Confidentiality statements were provided.]</i>
A. MATERIALS:	
1. Test material:	
<i>[Complete this subsection using the information provided in the methodology section of the study report. Name of test material as cited in the study report.]</i>	
Description:	<i>[e.g., Physical-chemical state of the test material.]</i>
Lot no./Batch no.:	<i>[Insert the test material's lot or batch number.]</i>
Nominal purity:	<i>[Insert the test material's nominal potency and/or concentration]</i>

Microbial Evaluation Templates

- Improved consistency between health and environment templates

New Health Template

I. MATERIALS AND METHODS	
A. <u>GUIDELINE FOLLOWED:</u> <i>[Indicate which guideline was followed most closely in testing.]</i>	
B. <u>MATERIALS:</u>	
1. <u>Test Material:</u>	<i>[as named in study]</i>
Description:	<i>[e.g. technical, nature, colour, stability]</i>
Lot/Batch#:	
Purity:	
CAS#:	
Storage conditions:	<i>[Describe how the test sample was stored and comment on the stability of sample under these conditions.]</i>
Microbiology:	<i>[Verification of concentration/homogeneity as necessary]</i>
2. <u>Sample Preparation:</u> <i>[Describe all sample preparation procedures.]</i>	
3. <u>Controls:</u> <i>[if applicable]</i> <i>[List all controls (e.g. heat-killed) and, if applicable, describe how the samples were prepared.]</i>	
4. <u>Test Animals:</u>	
Species:	
Strain:	
Age/weight at dosing:	
Source:	
Housing:	
Diet:	<i>[describe] ad libitum</i>
Water:	<i>[describe] ad libitum</i>
Environmental conditions:	Temperature: °C Humidity: % Air changes: /h Photoperiod: h dark/ h light

New Environment Template

I. MATERIALS AND METHODS:	
A. <u>GUIDELINE FOLLOWED:</u> <i>[Indicate which of the following guidelines were followed most closely in testing, and whether the guideline was developed for the toxicity testing of chemical agents or for the toxicity and infectivity/pathogenicity [or] toxicity testing of microbial agents. PMRA DIR 2001-02 Part 9.2¹ Environment Canada EPS 1/RM/44 Section 14.1¹ U.S. EPA 885.4050-Avian oral, Tier I¹ U.S. EPA 850.2100-Avian acute oral toxicity test² OECD Guideline 223 (Draft)²]</i>	
¹ Guideline designed to test acute oral infectivity and pathogenicity of microbial agents. ² Guideline designed to test acute oral toxicity of chemical agents.	
B. <u>MATERIALS:</u>	
1. <u>Test Material:</u>	<i>[Complete this subsection using the information provided in the methodology section of the study report. Name of test material as cited in the study report.]</i>
Description:	<i>[e.g., Physical-chemical state of the test material.]</i>
Lot/Batch#:	<i>[Insert the test material's lot or batch number.]</i>
Purity:	<i>[Insert the test material's nominal potency and/or concentration per unit weight or volume as indicated by the study sponsor.]</i>
Storage conditions:	<i>[Indicate how the test material was maintained, i.e., frozen, refrigerated, maintained in the dark, etc., and indicate whether the MPCA is stable under these conditions.]</i>
2. <u>Test Organism:</u>	
Species (common and scientific names): <i>[Insert names of species used in test.]</i> <i>PMRA DIR 2001-02 Preferably bobwhite quail (Colinus virginianus) or mallard duck (Anas platyrhynchos). Others acceptable, especially altricial species, with justification based on susceptibility to the MPCA or ecological considerations.</i> <i>Environment Canada EPS 1/RM/44 Mallard duck or northern bobwhite quail.</i>	

Microbial Evaluation Templates – Human Health

- Infectivity and Toxicity
 - Acute oral
 - Acute pulmonary
 - Intraperitoneal
 - Intravenous
 - Repeat dose inhalation
 - *In vivo* mammalian cell
 - Tissue Culture
- Toxicity or Irritation
 - Acute oral
 - Acute inhalation
 - Acute dermal
 - Dermal sensitization
 - Dermal irritation
 - Eye irritation
- Exposure
 - Occupational/Bystander
 - Dietary
- Miscellaneous
 - Reporting of hypersensitivity incidences
 - Genotoxic potential
 - Sensitivity of detection



Microbial Evaluation Templates – Environment

- **Infectivity and Toxicity**
 - Avian oral
 - Avian pulmonary, inhalation or injection
 - Wild mammals
 - Terrestrial arthropods
 - Honey bee
 - Terrestrial non-arthropod invertebrates
 - Terrestrial plants
 - Benthic aquatic arthropods
 - Pelagic aquatic arthropods
 - Aquatic non-arthropod invertebrates
 - Aquatic plants and algae
 - Freshwater fish
 - Estuarine fish
- **Fate**
 - Field studies

Microbial Evaluation Templates – OECD

- Templates were tabled for review and discussion by the OECD BPSG in 2004 and again in 2008
- PMRA received feedback from members (including U.S. EPA) and revised the templates
 - Developed new templates to accommodate EU requirements (e.g., repeat-dose inhalation)
- PMRA finalized templates in January 2010
- At the March 2011 BPSG meeting, members agreed to include the templates in the revised Microbial Dossier and Monograph Guidance Documents
 - Registrants can submit populated templates as OECD Tier II Summaries

Microbial Evaluation Templates

- Registrants can obtain microbial evaluation templates by contacting PMRA's publication office (publications@hc-sc.gc.ca) and requesting the Zip folder containing the templates which are in MS-Word format

<http://www.hc-sc.gc.ca/cps-spc/pest/registrant-titulaire/prod/templates-modeles-eng.php>



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Thank you!

